UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

DONNA M. TOMASIK and
PAUL L. TOMASIK,

Civil Action No.

Plaintiffs,

vs.

DEPUY ORTHOPAEDICS, INC.;
DEPUY, INC.;
DEPUY INTERNATIONAL LIMITED;
JOHNSON & JOHNSON;
JOHNSON & JOHNSON SERVICES, INC.;
JOHNSON & JOHNSON INTERNATIONAL,

Defendants.

Plaintiffs, by and through their attorneys, Faraci Lange, LLP, complaining of the defendants herein, respectfully allege to this Court upon and belief the following:

PARTIES

1. Plaintiffs are residents of the State of New York residing in Springville, Erie County, New York.

2. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is and was at all times relevant herein doing business in and/or having directed its activities at New York, and specifically this judicial district.

3. Defendant DEPUY, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw,

Indiana 46581. Defendant DEPUY, INC. is and was at all times relevant herein doing business in and/or having directed its activities at New York, and specifically this judicial district.

4. Defendant DEPUY INTERNATIONAL LIMITED is, and at all times relevant to this Complaint was, a British corporation organized under the laws of United Kingdom with its principal place of business on St. Anthony's Road, Beeston, Leeds, West Yorkshire LS11 8DT, United Kingdom. Defendant DePuy International, Ltd. is a resident and citizen of the United Kingdom. DePuy International, Ltd. designed, manufactured and sold the ASR Hip that is the subject of this lawsuit.

5. Defendant JOHNSON & JOHNSON is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON is and was at all times relevant herein doing business in and/or having directed its activities at New York, and specifically this judicial district.

6. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC. is and was at all times relevant herein doing business in and/or having directed its activities at New York, and specifically this judicial district.

7. Defendant JOHNSON & JOHNSON INTERNATIONAL is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON INTERNATIONAL is and was at all times relevant herein doing business in and/or having directed its activities at New York, and specifically this judicial district.

8. At all times relevant herein, Defendants, transacted, solicited, and conducted business in the State of New York, in particular, and derived substantial revenue from such business.

9. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling, and/or selling the subject product.

10. At all times relevant herein, Defendants expected or should have expected that its acts would have consequences within the United States, and in New York, in particular.

11. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the injured Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c).

GENERAL FACTUAL ALLEGATIONS

14. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

15. The Pinnacle Device is made up of four components: the metal femoral stem is inserted into the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabular cup (socket). The acetabular cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabular cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet" and/or the Pinnacle metal insert. The Pinnacle Device with an Ultamet liner and/or a Pinnacle metal insert is a "metal-on-metal" device due to the fact that both articulating surfaces – the femoral head (ball) and acetabulum liner (socket) – are comprised of cobalt-chromium alloy.

16. Defendants manufactured the Pinnacle Acetabular Cup System ("Pinnacle Device"), and launched it in or around 2001. The Pinnacle Device was designed, developed, and sold to replace damaged or diseased natural human hip joints.

17. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

18. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

19. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all

studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

20. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

22. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle Device metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that Defendants sold and implanted prior to the enactment of the MDA in 1976.

23. As such, under the 510(k) process, Defendants were able to market the Pinnacle Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

24. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered that the Pinnacle Device results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head rotates within the cobalt-chromium metal acetabular liner.

25. Defendants marketed the Pinnacle Device as having significant advantages over other hip devices and hip replacement systems. Defendants described the Pinnacle Device as "[u]niquely designed to meet the demands of active patients like you –and help reduce pain" and targeted its advertising to younger more active patients.

26. Defendants advertised the Pinnacle Device as a superior device featuring TrueGlide technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

27. Defendants also advertised and sold the Pinnacle Device as the best surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

28. On information and belief, Plaintiffs allege that Defendants sold approximately 150,000 Pinnacle Devices. Defendants stated in promotional material that "99.9% of Pinnacle Hip components are still in use today."

29. On information and belief, Plaintiffs allege that more than 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle Device.

30. On information and belief, Plaintiffs allege that Defendants are aware that the use of the Pinnacle Device may result in metallosis, biologic toxicity, and a high failure rate. Plaintiffs further allege that use of the Pinnacle Device results in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiffs further allege that Defendants are aware that metal particles from the Pinnacle Device results in metallosis, tissue death, bone erosion, and development of tumors.

31. Literature relating to Pinnacle Hips demonstrates that since at least 2006 DePuy was on notice of design problems showing that the Pinnacle metal-on-metal hip implant, like DePuy's ASR Hip, have a propensity to deform which can result in edge loading and loosening, and to cause increased wear and hence metal ion dispersion.

32. For example, an article published in September 2006, in the Journal of Arthroplasty, found that the stiffness of the Pinnacle cup lead to an exceptionally high rate of acetabular component deformation secondary to insertion, potentially caused by the press-fit technique. This study reported that an astounding "90.5% of [Pinnacle] cups had measurable compression deformity, averaging 0.16 +/- 0.16 mm. The corresponding forces acting on these cups averaged 414 +/- 421 N. For hard-on-hard bearing surfaces, such in vivo deformation of acetabular shells may result in negative clinical consequences such as equatorial loading with increased wear and potential seizing of components, chipping of ceramic inserts, or locking mechanism damage."

33. By way of another example, a study published in December 2010, in the Journal of Orthopaedic and Trauma Surgery reported that for patients implanted with metal-on-metal Pinnacle Hips (36-mm femoral head), serum levels of cobalt and chromium were found to be significantly increased at three (3) months postoperatively, compared to preoperative levels.

34. On information and belief, Plaintiffs allege that particulate debris from the Pinnacle Device causes metallosis, pseudotumors, cysts, severe inflammation, severe pain and discomfort, tissue and bone loss, lack of mobility and other related diseases.

35. The problems with the Pinnacle Device are similar to the issues that gave rise to Defendants' recall of their ASR XL Acetabular System and ASR Hip Resurfacing System. Like the Pinnacle Device, the ASR is also prone to early failure, and causes metallosis and cobalt toxicity resulting in serious health problems and the need for subsequent revision surgery. As a result, in August 2010, Defendants, in acknowledging the high failure rate of the ASR, recalled more than 93,000 ASRs worldwide. It is anticipated that Defendants will at some point recall or otherwise remove from the market the Pinnacle Devices for the same reasons.

36. On information and belief, the injured Plaintiff alleges that many recipients of the Pinnacle Device are suffering from elevated levels of chromium and cobalt. The injured Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Pinnacle Device have significantly elevated levels of chromium and cobalt in amounts many times higher than acceptable or recommended safety levels. Notably, the ASR and the Pinnacle Device were designed by the same orthopaedic surgeon, Dr. Thomas Schmalzried.

37. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle Device. For instance,

The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

38. On May 6, 2011 the FDA instructed manufacturers of metal-on-metal hip replacement systems to conduct post-market surveillance study of these devices, which include Defendants' Pinnacle Device.

39. On January 17, 2013, the FDA issued a proposed order requiring manufacturers of metal-on-metal total hip replacement systems to submit premarket approval applications, thereby preventing approval through the 510(k) process for these devices only.

40. Also on January 17, 2013 the FDA issued a Safety Communications to provide updated safety information and recommendations to patients and healthcare providers regarding metal on metal hip implants. Specifically, the FDA warned of the release of metal particles from the devices may cause damage to bone and/or soft tissue surrounding the implant and joint, which in turn can lead to pain, implant loosening, device failure, systemic reactions/issues and the need for revision surgery.

41. Despite public knowledge to the contrary, Defendants' continue to misrepresent the Pinnacle Device as a high-quality, safe and effective hip replacement product in their marketing and promotional materials even though Defendants have known for years that the Pinnacle Device poses a danger to patients that have it implanted.

42. As a result, Defendants continue to sell the Pinnacle Device to doctors who implant them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudotumors, and biologic toxicity, among other complications. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective device.

PLAINTIFF'S SPECIFIC FACTUAL ALLEGATIONS

43. The injured Plaintiff Donna M. Tomasik was born on April 1, 1954.

44. On or about March 24, 2008, the injured Plaintiff Donna M. Tomasik underwent a surgical procedure to implant a metal-on-metal Pinnacle Device in the right hip at Lake Shore Health Care Center in Irving, New York.

45. On or about November 5, 2009, the injured Plaintiff Donna M. Tomasik underwent a surgical procedure to implant a metal-on-metal Pinnacle Device in the left hip at Lake Shore Health Care Center in Irving, New York.

46. As a result of the implanted Pinnacle Device, the injured Plaintiff experienced debilitating pain, discomfort, and soreness, in the area of her hip implant, thereby, negatively affecting her ability to perform activities of daily living.

47. On information and belief, friction and wear between the cobalt-chromium metal head and cobalt-chromium metal liner caused toxic cobalt-chromium metal ions and particles to be released into the injured Plaintiff's blood, tissue and bone surrounding the implant.

48. Laboratory tests have confirmed that the injured Plaintiff has elevated cobalt and chromium levels in the blood as a result of the metal on metal abrasion problem associated with the Product.

49. On or about November 27, 2012, the injured Plaintiff underwent painful and risky revision surgery of the left hip to remove the defective Pinnacle Hip.

50. The injured Plaintiff continues to undergo monitoring of her right Pinnacle Hip.

51. In addition to the ordinary serious risks of surgery including infection, anesthesia risks, thrombosis to name a few, the revision surgery is especially dangerous because there is typically a reduced amount of bone in which to place the new hip implant. Due to the complexities involved, the revision surgery can also take longer than implant surgeries, and as the injured Plaintiff was in surgery for a prolonged period, she was and will be subject to the potential risks of surgery for a longer period of time. Recovery following a revision and long term prognosis are also negatively impacted by the additional surgery.

52. Due to the injured Plaintiff's need for revision surgery, the injured Plaintiff is now at a higher risk for dislocation then if the injured Plaintiff were to only have had the original hip replacement surgery and higher risk of an unsuccessful implant due to bone and tissue loss and injury.

53. Due to the metal on metal abrasion problem created by the device failure, she is at significant risk for injuries associated with metallosis, from the minute metal particles remaining in the injured Plaintiff's body and other complications from the toxicities of chromium and cobalt.

54. The injured Plaintiff's recovery from the replacement surgery is long and painful. The injured Plaintiff will continue to experience pain, and the injuries may be permanent and cause the injured Plaintiff additional complications in the future.

55. The injured Plaintiff continues to experience pain and discomfort following revision surgery, continues to have elevated cobalt and chromium levels and to have her right Pinnacle hip monitored.

56. All of the injuries and complications suffered by the injured Plaintiff were caused by the defective design, manufacture, marketing, sale, inadequate warnings, construction and unreasonably dangerous character of the Pinnacle Device that was implanted in the injured Plaintiff. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Device, the injured Plaintiff would not have consented to the Pinnacle Device being used in the injured Plaintiff's total hip arthroplasty.

57. As a foreseeable, direct, and proximate result of the wrongful acts and omissions of defendants, the injured Plaintiff was caused to suffer economic damages, severe and possibly permanent injuries, pain, suffering, mental suffering, and emotional distress.

FIRST CAUSE OF ACTION
NEGLIGENCE
(Against All Defendants)

58. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

59. Defendants had a duty to exercise reasonable care in designing, testing, manufacturing, marketing, promoting, selling and distributing the Pinnacle Devices and to warn health care providers and users of the risks, dangers and adverse side effects.

60. Defendants knew or should have known the Pinnacle Devices were unsafe when used as designed and manufactured and failed to exercise due care and were otherwise negligent

in the design, manufacture and marketing of this device including the failure to adequately test the product and the failure to provide adequate warnings.

61. The conduct of defendants was intentional, wanton, willful and outrageous beyond all standards of common decency and in reckless disregard and callous indifference to the public and users of the ASR Hip and sufficient to justify an award of punitive damages.

62. The limitations of liability set forth in New York's CPLR § 1601 do not apply to this action because defendants were engaged in intentional misconduct (CPLR § 1602.5), defendants acted with reckless disregard (CPLR § 1602.7), defendants acted knowingly and intentionally and in concert to cause the acts or failures upon which liability is based (CPLR § 1602-11).

63. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (MANUFACTURING DEFECT)
(Against All Defendants)

64. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

65. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

66. The Pinnacle Device that was surgically implanted in the injured Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product

specifications, posing a serious risk that it could fail early in patients giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery.

67. Defendants are strictly liable in tort to plaintiffs for designing, marketing, manufacturing and distributing a product that was defective and not reasonably safe for its intended use.

68. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (DESIGN DEFECT)
(Against All Defendants)

69. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

70. At all times herein, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle Device that was surgically implanted in the injured Plaintiff.

71. At all times herein, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as the injured Plaintiff that had the device surgically implanted.

72. At all times herein, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

73. At all times herein, a safer alternative design was feasible.

74. At all times herein, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

75. At all times herein, the Pinnacle Device's unsafe, defective, and inherently dangerous condition was a cause of injured Plaintiff's injuries.

76. At all times herein, Plaintiff's Pinnacle Device failed to perform as safely as expected when used in an intended or reasonably foreseeable manner.

77. The injured Plaintiff's injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

78. At all times herein, Plaintiff's Pinnacle Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

79. At all times herein, Plaintiff's Pinnacle Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

80. Defendants knew, or should have known, that Plaintiff's Pinnacle Device was defective, and was and is inherently dangerous and unsafe.

81. Defendants designed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

82. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (FAILURE TO WARN)
(Against All Defendants)

83. Plaintiff repeat and reallege each and every allegation previously set forth herein.

84. Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed and/or supplied the Pinnacle for sale and sold them to plaintiffs in the ordinary course of their business.

85. Defendants expected the Pinnacle Device to reach consumers in the State of New York, and it did reach consumers in New York, including plaintiffs, without substantial change in the condition.

86. Defendants failed to adequately warn the public, including plaintiffs, as well as physicians and surgeons of the risk of suffering the type and manner of injuries suffered by plaintiffs, which risks and/or danger were known or should have been known to the defendants and are liable to strictly liable to plaintiffs because their product was not reasonably safe for its intended use.

87. Defendants knew or should have known that the Pinnacle Device were defective and dangerous and showed reckless indifference to or conscious disregard for the plaintiffs' safety by failing to provide proper warnings to the public and the medical community.

88. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

89. Plaintiff repeats and realleges each and every allegation previously set forth herein.

90. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Pinnacle Device.

91. Defendants expressed in their literature, advertisements, promotions and through representations by their marketing team and sales agents that Pinnacle Hips were safe, effective and fit for use in Pinnacle surgeries for which they were designed, manufactured and marketed.

92. By making such representations, defendants expressly warranted that the Pinnacle Hips were safe and effective, and fit for the uses for which they were designed, marketed, manufactured and distributed.

93. As explained above, in fact, the Pinnacle Hips were not safe, effective, fit nor proper for the use for which they were designed, manufactured and marketed.

94. Plaintiff, and her healthcare providers, and the medical profession relied on defendants' express warranties.

95. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(Against All Defendants)

96. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

97. Upon information and belief, on or around November 5, 2009, injured Plaintiff received and began using a Pinnacle Hip to replace her natural left hip manufactured by defendants.

98. Upon information and belief, on or around March 24, 2008, injured Plaintiff received and began using a Pinnacle Hip to replace her natural right hip manufactured by defendants.

99. Defendants impliedly warranted that the Pinnacle Devices were merchantable pursuant to UCC § 2-314 and suitable for the ordinary purpose for which it was intended to be used in Pinnacle surgeries.

100. Defendants Pinnacle Devices were not merchantable nor reasonably suited for the ordinary purpose for which they were being used.

101. As a result, defendants breached UCC § 2-314.

102. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF FITNESS
(Against All Defendants)

103. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

104. Defendants impliedly warranted, pursuant to UCC § 2-315, that the Pinnacle Devices were fit for a particular purpose for which they were being used, Pinnacle surgeries.

105. Defendant's Pinnacle Devices were not fit for the particular purpose for which they were being used.

106. As a result, defendants breached UCC § 2-315.

107. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

NINTH CAUSE OF ACTION
VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349
(Against All Defendants)

108. Plaintiffs repeat and reallege each and every allegation previously set forth herein.

109. Defendants engaged in commercial conduct by selling Pinnacle Devices and misrepresented and omitted material information regarding products by failing to disclose the known risks of their Pinnacle Devices.

110. By failing to disclose the known dangers and risks of the Pinnacle Devices, defendants engaged in unfair and deceptive consumer-oriented acts.

111. Reasonable consumers, including injured Plaintiff, were injured by defendants' unfair and deceptive acts.

112. As a direct and proximate result of the wrongful acts and omissions of defendants, plaintiff suffered economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered these serious and dangerous side effects.

TENTH CAUSE OF ACTION
LOSS OF CONSORTIUM
(Against All Defendants)

113. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth herein:

114. Plaintiff Spouse Paul L. Tomasik ("Plaintiff Spouse") is and at all times relevant hereto has been the lawful spouse of Plaintiff Spouse and as such Plaintiff Spouse is entitled to the comfort and enjoyment of his society and services.

115. By reason of the foregoing, Plaintiff Spouse has necessarily paid and has become liable to pay for medical aid, treatment and for medications and other liabilities.

116. By reason of the foregoing, Plaintiff Spouse has been caused, presently and in the future, the loss of the spouse's companionship, services, society and the ability of said plaintiff

spouse in said respect has been impaired and depreciated, and the material association between husband and wife has been altered, and as such, the Plaintiff Spouse has been caused mental anguish and suffering.

117. As a direct and proximate result of the foregoing misconduct of the defendants, Plaintiff Spouse has been deprived of his spouse's companionship, services, solace, consortium, affection and has suffered damages as aforesaid.

WHEREFORE, plaintiffs demand judgment against the defendants, and each of them, individually, jointly and severally and requests compensatory damages in a sum in excess of $75,000, together with punitive damages, interest, attorneys fees, cost of suit, and all such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for the following relief:

A. Judgment in favor of plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Punitive and/or exemplary damages in such amounts as may be proven at trial;

D. Attorneys' fees and costs;

E. Pre- and post-judgment interest; and

F. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: August 9, 2013

Respectfully Submitted,
FARACI LANGE, LLP

By: /s/ Hadley L. Matarazzo
Hadley L. Matarazzo
28 E. Main Street, Suite 1100
Rochester, New York 14614
Telephone: (585) 325-5150
Fax: (585) 325-3285
hmatarazzo@faraci.com

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Dated: August 9, 2013

Respectfully Submitted,
FARACI LANGE, LLP

By: /s/ Hadley L. Matarazzo

Hadley L. Matarazzo
28 E. Main Street, Suite 1100
Rochester, New York 14614
Telephone: (585) 325-5150
Fax: (585) 325-3285
hmatarazzo@faraci.com